REMARKS

Applicants traverse all objections, rejections and assertions made by the Examiner in response to the Office Action mailed April 1, 2002. Entry of the amendments and favorable reconsideration is respectfully requested.

The Examiner requested Applicants to indicate whether or not *Messerschmidt* be listed as an applicant in the instant application. Applicants assert that *Messerschmidt* is not an inventor in the instant application.

The Examiner requested information regarding identifying the references known to Applicant that disclose similar subject matter. Applicants have submitted Information Disclosure Statements and will continue to do so as references are discovered in accordance with 37 C.F.R. § 1.56.

Drawing Objection

The drawings were objected to under 37 CFR § 1.83(a) as not showing every feature of the invention specified in the claims. Applicants traverse the rejection.

Applicants have provided new Figures 4-7 showing every feature of the invention specified in the claims. Withdrawal of the objection is respectfully requested.

Specification Objection

The specification was objected to as missing a serial number at page 24. Applicants have amended the specification updating issued patent numbers and providing the missing information at page 24. Withdrawal of the rejection is respectfully requested.

The Examiner has objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. The present specification teaches the basis for using an index matching fluid that has an index of refraction close to that of tissue at 1.38:

"Absent the index matching fluid of the present invention, [the optical interface between tissue and the optical element] can include gaps which are air filled and cause detrimental refraction of light going into the tissue and exiting the tissue. Thus any index matching fluid having a refractive index closer to that of the tissue at about 1.38 versus the refractive index of air of about 1.0 would provide an improved interface" (page 16, line 21 through page 17, line 2).

Robinson et al. (U.S. Patent No. 6,152,876 and incorporated in the present application by reference on page 3, lines 11) teaches, "The index matching medium preferably has a refractive index of between 1.30 – 1.45, more preferably between 1.35 – 1.40. Utilization of a refractive index in this range has been found to improve the repeatability and accuracy of the above method [of using an index matching fluid] by improving the optical throughput and decreasing spectroscopic variations unrelated to analyte concentration" (column 9, lines 16-22).

The particular statement that the examiner quotes, "a refractive index of about 1.38," page 13, line 1, pertains the family of oil products known FLUOROLUBE, produced by Occidental Chemical. The index of refraction of these oils is known by one of skill in the art. Thus, Applicant asserts that a claimed range between 1.30 and 1.45 has antecedent basis. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph:

The Examiner has rejected claims 1-19 under 35 U.S.C. § 112, first paragraph, as the specification does not enable the claims. The Examiner asserts that the use of "index matching-medium" as described at page 9, line 22, is critical or essential to the practice of the invention, but not included in the claims. Applicants traverse the rejection.

Applicants refer the Examiner to MPEP § 2164.08(c), wherein the application of the decision of In re Mayhew is discussed in detail. It is stated that in determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. Applicants believe that the Examiner has not taken into consideration the entire disclosure in drawing a conclusion that the index-matching medium is critical or essential. It is further stated in MPEP § 2164.08(c), that limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from the claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

Messerschmidt asserts that an "index-matching medium" is not essential or critical to the practice of the invention under the standard set forth in MPEP §2164.08(c). Applicants demonstrate the non-criticality of the index-matching medium by at least the following evidence:

(1) the specification discloses at least two alternatives to the index-matching medium,

(2) the original claims in the present application and the *Messerschmidt* application did not require an "index-matching medium",

(3) the original specification did not require an "index-matching medium",

(4) *Messerschmidt* did not indicate that an "index-matching medium" is essential or critical, but refer to it as a "key" when discussing a preferred embodiment.

The summary of the present application does not specify the specific use of an index matching fluid. Rather, use of an index matching fluid is taught in the detailed description as one preferred embodiment of an apparatus and method for acquiring tissue spectra.

In the present application, the summary of the invention states that, "Success of the method of the present invention is believed tied to two components. First, the method incorporates an apparatus and technique for accurately and repeatably acquiring a tissue spectrum which is stable while remaining sensitive to slight changes in spectral output at any given wavelength" (page 5, lines 5-8). Furthermore, *Robinson et al.* (U.S. Patent No. 6,152,876 and incorporated in the present application by reference on page 3, lines 11-15) states, "the difference between the two traces [50 and 52 of figure 3, which is the same figure as in the present application] can be attributed largely to spurious energy from specular contamination" (column 18, lines 42-44).

There are numerous methods known to one of knowledge in the art to obtain accurate and repeatable tissue spectra by reducing specular contamination. For example, *Messerschmidt et al.* (U.S. Patent No. 5,935,062 and incorporated in the present application by reference on page 3, line 21 through page 4, line 7) teaches an apparatus for reducing specular contamination of diffusely reflected tissue spectra: "the thick blocker blade of the present invention may substantially prevent the specularly reflected component of light from reaching the spectroscopic analyzer" (column 7, lines 59-62). In a different patent by *Messerschmidt et al*, (U.S. Patent No. 5,636,633 and incorporated in the present application by reference on page 3 line 16), the inventors teach a different apparatus for reducing specular light based on symmetrical optics:

"The apparatus incorporates a specular control device which separates the specularly reflected light or surface reflected light from the diffusely reflected light returning from deep within the tissue. Therefore, only diffusely reflected light containing analyte information reaches the spectroscopic analyzer" (column 6, lines 8-13). Also, "the use of a specular control device based on symmetric distribution of the input and output optics can reduce or eliminate specular light contamination associated with diffuse reflectance sampling of human tissue" (column 6, lines 21-25).

As such, the present application teaches several different methods and apparatuses to obtain tissue spectra of sufficient quality to perform identification determination tasks. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph:

Claims 3 and 23 have been rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants traverse the rejection.

The Examiner states that it is unclear what is meant by "patients difference" in claim 3 as the term patient does not have an antecedent basis and, thus, it is not clear if the patients are same as the claimed "verified individuals" or "target individuals" as recited in the preamble of claim 1.

"Patients' differences" refers to the "difference spectrum, $D(\nu)$, [generated] using the spectrum just collected from the person wishing authorization, $V(\nu)$, and the prestored authorized spectrum, $A(\nu)$, or spectra corresponding to the person whose identification was stated: $D(\nu) = V(\nu) - A(\nu)$" (page 22, lines 11 – 14), or "other mathematical operations of a similar nature" (page 22, line 20).

The "model that identifies between patient's differences" refers to the mathematical methods that the present application teaches to define "underlying spectral shapes" (page 23, line 20) that are applied to the difference spectrum to determine consistency with known intra-patient [or intra-person] spectral features and thus authenticating or denying identity authentication (page 23, lines 11-17). Modeling methods include "simple spectral decomposition" (page 24, line 2), "generic model[ing]" (page 24, line 5), and "simulated constituent variation" (page 24, line 12). As well, "linear and nonlinear discriminant analysis" (page 29, line 6) can be used to

generate a model whose factors are "useful in clustering the intra-person data points together, while separating the intra-person clusters at a large inter-person distance apart." (page 29, lines 3-4) using techniques know to one of skill in the art. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 23 requires an "index-matching medium" that has a "refractive index between and about 1.30 and 1.45". The Examiner states the term "about" in Claim 23 renders this claim indefinite. In addition, the entire claim range of 1.30 and 1.45 is not founded in the specification as described in the objection above.

Applicants direct the Examiner to MPEP § 2173.05(b)A where the term "about" is discussed as being clear but flexible. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections

Rejections under 35 U.S.C. § 102(b):

Ott

Claims 1, 2, 5, 7 and 8 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Ott*. Applicants respectfully traverse the rejection.

Ott teaches a method of applying sonic energy (column 1, lines 41-42) to a part of the body such as a bone in the arm (e.g., ulna, column 3, line 37) to measure the mechanical vibratory (column 3, line 58) transfer characteristics of the body part and compare this signal to one on record. The sensors associated with such an apparatus are electromechanical (column 3, line 46). As such, the method and apparatus of *Ott* is based on mechanical properties of bones and other body parts.

The claimed method and apparatus of the present invention pertain to tissue spectroscopy, which uses optical radiation in the visible, near infrared and mid-infrared ranges (page 4, lines 21-23), a plurality of wavelengths of which passes through skin tissue, preferably tissue below the epidermis (page 5, line 21-23). The sensor used for such measurements is an optical system capable of measuring the optical intensity at a plurality of wavelengths ("spectrometer", page 7, line 1). As such, the claimed methods and apparatus of the present

application are based on the optical characteristics of skin and other tissues. For at least these reasons, this reference does not anticipate the claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

Prokiski et al.

Claims 1, 2, 5-8 and 12-14 were rejected as being anticipated by *Prokoski et al.* Applicants traverse the rejection.

Prokiski et al. teach a method of collecting and processing "a thermal image of a portion of an individual's body" (column 3, lines 21-22). The resulting image is processed to define the "contours of the unique structural features of the individual" (column 3, lines 29-31), "such as the eye and nose area of the individual's face" (column 3, lines 33-34). An infrared imager such as a "platinum salicide staring array camera" (column 4, lines 43-44) is used to collect such data. As known to one of skill in the art, infrared imagers such as these typically operate within "atmospheric transmission windows" in a mid-infrared region where there are also significant mid-infrared emissions such as the "3-6 or 8-14 micron ranges" specified by *Prokoski et al.* (column 4, line 51). The method and apparatuses taught by *Prokoski* do not incorporate or rely on any feature that measures the infrared light at multiple different wavelengths. As such, the methods and apparatuses of *Prokoski et al.* are monochromatic, image-based means for identifying people based on external features.

The claimed methods and apparatuses of the present invention rely on measurements of a "plurality of wavelengths" (claim 1, and page 7, line 2) of light that are preferably from light that is "diffusely reflected from the inner dermis rather than the epidermis (page 5, lines 22 –23). The embodiments described use spectrometers such as "Fourier Transform system[s]" (page 19, line 4), and other "dispersion type instruments" (page 19, line 7) that do not form an image. As such, the identifying information taught by the present application is conveyed in the intensity of light measured at a plurality of wavelengths. For at least these reasons, this reference does not anticipate the claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

Stoianov et al.

Claims 1-4 were rejected as being anticipated by *Stoianov et al.* Applicants traverse the rejection.

Stoianov et al. teach a method and apparatus for using frustrated total internal reflection to collect an image that is related to the "finger print image" (column 3 line 13). The fingerprint features of interest are spatially distributed on the surface of the fingertip. The illumination source for this system is monochromatic ("coherent light" column 1, line 60). The Fourier transform that is taken of the resulting image is a spatial Fourier transform (column 3, lines 19 and 20) consisting spatial frequencies (column 3, lines 22-23) and spatial amplitude and phase information (column 3, line 39). As such, *Stoianov et al.* teach a novel method for collecting and processing fingerprint images as the basis for a biometric determination.

The claimed methods and apparatuses of the present invention are based on the measurement of the optical properties of tissue measured at a plurality of wavelengths (claim 1, page 7, line 2). The properties of interest exist below the external surface (epidermis) of the skin (page 5, lines 22-23). Multiple skin locations can be used for this measurement (page 15, lines 11-12) and no image of the skin site is required. The Fourier spectrometer (page 30, line 4) used in one embodiment of the present invention effectively performs a Fourier transform with respect to optical frequencies of light passing through it, as known to one of skill in the art. For at least these reasons, this reference does not anticipate the claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102(e):

Claims 1, 10, 11 and 14 were rejected under 35 U.S.C. § 102(e) as being anticipated by *Toyoda et al.* Applicants traverse the rejection.

Toyoda et al. teach an apparatus and method for comparing two patterns that contain identifying information about an individual. Specifically, *Toyoda et al.* teach a method and apparatus to perform a mathematical correlation between two patterns to determine the degree of similarity. As *Toyoda et al.* teach, the correlation of these two signals (equation 1, column 7, line 40) can alternatively be formulated as a function of the Fourier Transforms of each of the signals (equation 2, column 7, line 55). Thus, the Fourier spectra that *Toyoda et al.* refer to are spatial

Fourier spectra of a fingerprint image. *Toyoda et al.* do not mention multiple wavelengths in this regard. As such, *Toyoda et al.* teach methods and apparatuses to compare two monochromatic images (especially fingerprint images) using a correlation-based methodology.

The claimed methods and apparatuses of the present invention are based on the measurement of the optical properties of tissue measured at a plurality of wavelengths (claims 1, 14 and page 7, line 2), resulting in optical spectra. The means taught to determine similarity between two optical spectra are based on a variety of discrimination techniques including linear and non-linear discriminant analysis (page 29, lines 2-6), as well as using standard spectral metrics such as Mahalanobis distance and spectral residuals (page 23, line 22). For at least these reasons, this reference does not anticipate the claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103(a):

Claims 1, 12, 13 and 19-23 were rejected under 35 U.S.C. § 103(a) over the combination of *Messerschmidt*, *Robinson et al.* and *Peterson et al.* Applicants traverse the rejection.

Messerschmidt teaches a method and apparatus for performing noninvasive measurements of an analyte in tissue (column 5, line 49) using multivariate techniques such as partial least squares (column 8, line 10) to produce a quantitative estimate of the amount of a substance (e.g., glucose) present in a sample (column 13, line 59). Such multivariate techniques establish a mathematical relationship between the spectral data and the analyte estimate of interest by using a set of calibration data (column 13, line 52). The calibration data consist of a set of optical spectra taken on samples with known amount of the analyte of interest (column 13, line 53) which is then used to determine a mathematical relationship between the spectra and the analyte estimates known as a calibration model (column 13, line 52). Once such a model is determined, it is applied to future optical spectra with unknown analyte values to produce the analyte estimate (Robinson, column 5, line 5).

The present claims are directed to methods and systems for determining individual identity using optical tissue spectra. Calibration data used for these determinations are contained within a calibration spectral difference database (page 22, line 22) that is taken on one or more people measured multiple times each (page 23, line 2). The calibration method of the present

invention relies on a discrimination analysis (page 23, line 19) to confirm that the spectral difference (page 23, line 11) is consistent with the calibration spectral difference database (page 23, line 12). In order to do so, the analysis applied to the calibration spectral database seeks to determine underlying spectral features or shapes (page 23, line 20) within the calibration data. Other methods of applying linear and nonlinear discriminant analysis may also be used (page 29, lines 2-6).

Peterson et al. teach an apparatus for collecting an "image" (column 2, line 2) of "subcutaneous objects and characteristics" (column 2, line 14). In order to do so, *Peterson et al.* teaches that the array of light detectors must have a "minimum density of 625 elements per square inch arranged in a square matrix" (column 2, line 58). *Peterson et al.* also state that the corresponding grid of LED illuminators consists of "two wavelengths . . . being of 720-750 nanometers and . . . between 850 and 1000 nanometers" (column 3, line 16). Of note, *Peterson et al.* do not disclose the method by which the two kinds of LEDs are illuminated (simultaneously, alternately, one-by-one sequentially, etc.), and refer to the illumination light in the singular (e.g. "a grid of light-emitting elements of a wavelength", claim 2; "emitting a light", claims 1 and 6). Furthermore, *Peterson et al.* do not provide for a system to measure the intensity of a plurality of wavelengths of light (see Figure 1) by use of gratings, prisms, Fourier Transform spectrometers or other apparatuses and methods known to one of skill in the art.

The claims are directed to methods and systems for identity determinations that are based on the optical properties of skin measured at a plurality of wavelengths (claim 1, 19, and page 4, line 18). The present invention does not rely on an image of the tissue to be taken: the spectrometer (Perkin Elmer 2000, page 30, line 5) referred to in the Experimental Results section is a non-imaging spectrometer with a single detector element.

MPEP § 2143.01 provides: "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Applicants assert that this requisite motivation to combine the references is not present in the cited references. MPEP § 2143.02 states that a reasonable expectation of success must be present to combine references. Applicants assert the requisite expectation of success to combine the references is not present.

The references fail to provide motivation to one of ordinary skill in the art to combine the references. The Examiner states that one would use the spectral analyte method of *Messerschmidt* or *Robinson et al.* for the purposes of identifying a target individual as taught by *Peterson et al.* in order to provide *Messerschmidt* with the additional and beneficial function of "reliably" detecting the identity of an individual using a method that is "not easily tampered with", is inexpensive and "can be used or readily placed in a large variety of structures without a great deal of physical alteration". These statements found in *Peterson et al.* are irrelevant to *Messerschmidt*. *Messerschmidt* is solely concerned with analyte concentrations in **any** tissue sample not with identifying specific tissue samples.

There is no expectation of success that the analyte method of *Messerschmidt* could be modified to identify individuals. Indeed, the Examiner failed to provide any evidence of a reasonable expectation of success to combine the references.

For at least these reasons, these references do not render the claimed invention obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Ott* and *Dolfing

The examiner has rejected claim 14 as obvious with respect to the combination of *Ott* and *Dolfing* under 35 U.S.C. § 103(a). Applicants traverse the rejection.

Ott teaches a method of applying sonic energy (column 1, lines 41-42) to a part of the body such as a bone in the arm (e.g., ulna, column 3, line 37) to measure the mechanical vibratory (column 3, line 58) transfer characteristics of the body part and compare this signal to one on record. The sensors associated with such an apparatus are electromechanical (column 3, line 46). As such, the method and apparatus of *Ott* is based on mechanical properties of bones and other body parts.

The claimed method and apparatus of the present invention pertain to tissue spectroscopy, which uses optical radiation in the visible, near infrared and mid-infrared ranges (page 4, lines 21-23), a plurality of wavelengths of which passes through skin tissue, preferably tissue below the epidermis (page 5, line 21-23). The sensor used for such measurements is an optical system capable of measuring the optical intensity at a plurality of wavelengths ("spectrometer", page 7, line 1). As such, the claimed methods and apparatus of the present

application are based on the optical characteristics of skin and other tissues. Thus, *Ott* fails to disclose or suggest the claimed invention.

Dolfing fails to remedy the shortcomings of *Ott* described above. For at least these reasons, the references do not render the claimed invention obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Messerschmidt, Robinson et al., Peterson et al.* in view of *Hoshino et al.

Claims 15-17 are rejected under 35 U.S.C. § 103(a) over *Messerschmidt, Robinson et al., Peterson et al.* in view of *Hoshino et al.* Applicants traverse the rejection.

The Examiner applies *Hoshino et al.* as utilizing the purported identity of the target individual. *Hoshino et al.* fail to remedy the shortcomings of *Messerschmidt, Robinson et al., Peterson et al.* as described above. For at least these reasons, the references do not render the claimed invention obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Prokoski et al.* in view of *Hoshino et al.

Claims 15-17 are rejected under 35 U.S.C. § 103(a) over *Prokoski et al.* in view of *Hoshino et al.* Applicants traverse the rejection.

The Examiner applies *Hoshino et al.* as utilizing the purported identity of the target individual. *Hoshino et al.* fail to remedy the shortcomings of *Prokoski et al.* as described above. For at least these reasons, the references do not render the claimed invention obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Ott* and *Itsumi et al.

Claim 9 is rejected under 35 U.S.C. § 103(a) over the combination of *Ott* and *Itsumi et al.* Applicants traverse the rejection.

The Examiner applies *Itsumi et al.* as disclosing adding the target spectrum to the authorization spectra after verification. *Itsumi et al.* fail to remedy the shortcomings of *Ott* as described above. For at least these reasons, the references do not render the claimed invention obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Messerschmidt, Robinson et al., Peterson et al.* and *Hoshino et al.*, in further view of *Toyoda et al.

Claim 18 is rejected under 35 U.S.C. § 103(a) over the combination of *Messerschmidt, Robinson et al., Peterson et al.* and *Hoshino et al.*, in further view of *Toyoda et al.* Applicants traverse the rejection.

The Examiner applies *Toyoda et al.* as disclosing calculating spectral differences between spectra. *Toyoda et al.* fail to remedy the shortcomings of *Messerschmidt, Robinson et al., Peterson et al.* and *Hoshino et al.*, as described above. For at least these reasons, the references do not render the claimed invention obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

While additional features of the claims further distinguish these claims from the cited reference, a detailed discussion of this is believed to be unnecessary at this time in view of the basic differences pointed out by the Examiner.

Applicants respectfully request withdrawal of the objections and rejections and allowance of the claims. Should the Examiner feel a telephone interview would be helpful in advancing this case to allowance, Applicants invite the Examiner to contact the representative at the number listed below.

Respectfully submitted,

ROBERT K. ROWE ET AL.

By their Attorney,

Date: 6/28/02

David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
331 Second Avenue South, Suite 895
Minneapolis, Minnesota 55401-2246
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

Please make the following amendments to the specification as follows:

Please replace the paragraph spanning lines 4-8 on page 1 of the application with the following:

> The present application is related to U.S. Patent ~~Application Serial~~ No. ~~09/174,812~~ 6,152,876, filed October 19, 1998, entitled "Method for Non-Invasive Analyte Measurement with Improved Optical Interface", and U.S. Patent ~~Application Serial~~ No. ~~08/871,366~~ 5,935,062, filed June 9, 1997, entitled "Diffuse Reflectance Monitoring Apparatus", both assigned to the same assignee as the present application.

Please replace the paragraph spanning lines 3-15 on page 3 of the application with the following:

> Improved methods and apparatus for gathering and analyzing a near-infrared tissue spectrum for an analyte concentration are disclosed in commonly assigned U.S. Patent applications and issued patents. U.S. Patent No. 5,655,530 and U.S. Patent ~~Application Serial~~ No. ~~08/844,501~~ 5,823,951, filed April 18, 1997, entitled "Method for Non-invasive Blood Analyte Measurement with Improved Optical Interface" relate to near-infrared analysis of a tissue analyte concentration which varies with time, with a primary focus on glucose concentrations in diabetic individuals. The methods and apparatus include placing a refractive index-matching medium between a sensor and the skin to improve the accuracy and repeatability of testing. U.S. Patent ~~Application Serial~~ No. ~~09/174,812~~ 6,152,876, filed October 19, 1998, entitled "Method for Non-Invasive Blood Analyte Measurement with Improved Optical Interface" discloses additional improvements in non-invasive living tissue analyte analysis. The disclosure of each of these three applications or patents are hereby incorporated by reference.

Please replace the paragraph spanning line 16, page 3 to line 7, page 4 of the application with the following:

> U.S. Patent No. 5,636,633 relates, in part, to another aspect of accurate non-invasive measurement of an analyte concentration. The apparatus includes a device having transparent and reflective quadrants for separating diffuse reflected light from specular reflected light. Incident light projected into the skin results in

specular and diffuse reflected light coming back from the skin. Specular reflected light has little or no useful information and is preferably removed prior to collection. U.S. Patent ~~Application Serial~~ No. ~~08/871,366~~ 5,935,062, filed June 9, 1997, entitled "Improved Diffuse Reflectance Monitoring Apparatus", discloses a further improvement for accurate analyte concentration analysis which includes a blocking blade device for separating diffuse reflected light from specular reflected light. The blade allows light from the deeper, inner dermis layer to be captured, rejecting light from the surface, epidermis layer, where the epidermis layer has much less analyte information than the inner dermis layer, and contributes noise. The blade traps specular reflections as well as diffuse reflections from the epidermis. The disclosures of the above patent and application, which are assigned to the assignee of the present application, are also incorporated herein by reference.

Please replace the paragraphs spanning lines 19-23, page 7 of the application with the following:

-- Fig. 2 is a partial cross-sectional view of an alternative embodiment of a sensor element coupled to opposite sides of a skin surface via an indexing-matching fluid; [and]

Fig. 3 is a graphical representation of experimental data showing the improvement in accuracy and repeatability of a sensor coupled to the skin via an index-matching medium[.]; --

Please insert the following paragraphs beginning at line 24, page 7 of the application as follows

--Fig. 4 is a block diagram describing an identification procedure using near-infrared tissue analysis;

Fig. 5 depicts an alternate identification procedure using near-infrared tissue analysis;

Fig. 6 is a functional diagram of the identification system; and

Fig. 7 is a block diagram representing the configuration of the system.--

Please replace the paragraphs spanning line 14, page 3 to line 2, page 15 of the application with the following:

In both embodiments depicted in Figs. 1 and 2, an output sensor 26 is utilized to receive reflected or transmitted light energy from the tissue 10. In a preferred embodiment, a specular control device is incorporated to separate the specular reflected light from diffusely reflected light. Such devices are disclosed in co-pending and commonly assigned U.S. Patent ~~Application Serial~~ No. ~~08/871,366~~ 5,935,062, filed June 9, 1997, and entitled "Diffuse Reflectance

Monitoring Apparatus", the disclosure of which is incorporated herein by reference. As described in conjunction with a method of analysis below, the embodiment of Fig. 1 has an output sensor 26 which receives reflected light energy, while the embodiment of Fig. 2 includes an output sensor 26 which receives transmitted light through the tissue 10. As with the input element 20, the output element 26 is preferably an optical lens. Other optical collection means may be incorporated into an output element 26, such as a multiple lens system, tapered fiber, or other beam-collection means to assist in directing the light energy to the spectrum analyzer 30.

Please replace the paragraphs spanning line 20, page 21 to line 13, page 22 of the application with the following:

-- In a preferred method as represented in Figure 5, the verification task is implemented when a person seeks to perform an operation for which there are a limited number of people authorized (e.g., perform a spectroscopic measurement, gain entry into a room, achieve control over an interlocked vehicle or piece of machinery, etc.). The person's NIR spectral data 500 is used for verification of the person's identity. In this preferred method, the person uses a spectroscopic measurement device to collect one or more tissue spectra 510. Before, during, or after the measurement, the person also states who they are (e.g. "person X") by some means (personal ID number, name, badge, etc.). The verification task is then the confirmation 530 that the person is who they stated by comparison of the near-infrared spectrum with one or more previously recorded and verified spectra from person X. Equivalently, if the verification task is associated with an operation for which only a single person is authorized, then the task simplifies to an assurance that the sole authorized individual is attempting the operation.

In analyzing the data 520, all ~~All~~ preferred implementations of the proposed verification methodology generate a difference spectrum, D(ν), using the spectrum just collected from the person wishing authorization, V(ν), and the prestored authorized spectrum, A(ν), or spectra corresponding to the person whose identification was stated:--

Please replace the paragraph spanning lines 4-10 on page 24 of the application with the following:

The second method of generating underlying spectral shapes relates to the development of a generic model as described in co-pending U.S. Patent ~~Application Serial~~ No. 6,157,041 _____ filed on even-date herewith, entitled "Methods and Apparatus for Tailoring Spectroscopic Calibration Models," the disclosure of which is incorporated by reference. In this application, the underlying spectral shapes are generated through a calibration procedure performed on intra-patient spectral features. The calibration is based upon measured analyte concentration features.

Please replace the paragraphs spanning line 22, page 22 to line 3, page 24 of the application with the following:

--The other key element of a preferred verification method as shown in Figure 6 is a spectral difference database 600 that was developed using the same mathematical operation as used for generating D(ν). The spectral differences (or ratio, etc.) in the ~~authorization~~ spectral difference database are preferably formed from one or more people measured multiple times each 610. For robustness, the sampling of an individual person should span expected changes in the person's physiology, expected changes in or across the spectroscopic measurement devices, and changes in the measurement environment. In one preferred embodiment, spectral differences can be generated in a multitude of combinations of spectra from a given person, but should never be formed using spectra from different people. By filling the database with intra-patient difference spectra, typical inter-patient spectral differences are removed, and the resulting database contains only intra-patient spectral features as well as instrumental and environmental effects.

The verification task is accomplished through determining if the spectral difference, D(ν), is consistent with the spectral difference database 600 for the individual. If the identification that the person stated is accurate, the resulting difference spectrum, D(ν), will contain only intra-patient spectral features 620, and thus, be consistent with the database. Conversely, if the identification is not accurate, D(ν) will contain inter-patient spectral features and be incompatible with the intra-patient spectral difference database for the individual, indicating that the verification failed 630. ~~In this case, the verification will fail.~~

As shown in Figure 7, consistency ~~Consistency~~ with the database 710 can be ascertained in a variety of ways. In preferred methods discriminant analysis techniques 720 incorporated in ~~computer~~ programs 730 of a computer 700 are used. These methods rely upon establishing the underlying spectral shapes (factors, loading vectors, eigenvectors, latent variables, etc.) in the spectral database, and then using standard outlier methodologies (spectral F ratios, Mahalanobis distances, Eucliden distances, etc.) to determine the consistency of D(ν) with the database. The underlying spectral shapes can be generated by multiple means as disclosed herein. First, the underlying spectral shapes can be generated based upon simple spectral decompositions (eigen analysis, Fourier analysis, etc.).--

Please replace the paragraph spanning lines 7-22 on page 29 of the application with the following:

-- In one method depicted in Figure 4, when identity verification is desired, a tissue spectrum 400 and purported identity are obtained 440 from the target individual. The tissue spectrum is ~~operated on~~ calculated 460 to generate the same factors used to cluster the calculated datapoints 450 in the spectral database. The spectral difference 420 between the target spectrum and the database spectra are calculated. One calculation measures the Mahalanobis distance between the target spectrum and the database spectra for the purported

identity. If the distance is less than a threshold distance, then the purported identity can be positively verified 410. Another spectral difference includes computing a spectral residual, or difference spectrum between the target spectrum and a cumulative spectrum, for the purported individual from the database. In evaluating 430 ~~If~~ the spectral residual, the identity can be positively identified if the residual is less than a preset threshold~~, then the identity can be positively identified~~. In one method, both the spectral residual and a difference, such as the Mahalanobis distance, must be below their respective thresholds before identity is positively established. In one method, threshold values were set for both spectral distance and spectral residual magnitude to include 99% of the database spectra. In another method, threshold values were set for both spectral distance and spectral residual magnitude to include 95% of the database spectra.--